

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION**

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MDL NO. 1456

CIVIL ACTION: 01-CV-12257-PBS

**THIS DOCUMENT RELATES TO
ALL ACTIONS**

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Judge Patti B. Saris

**DEFENDANTS' STATUS REPORT AND MEMORANDUM
ON THE MEDICARE FEDERAL QUESTION ISSUE
PENDING IN THE CASES TRANSFERRED TO THIS COURT**

On behalf of the defendants in the Connecticut and New York Attorney General actions,¹ defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK") respectfully submits this Status Report and Memorandum on the Medicare Federal Question Issue Pending in the Cases Transferred to this Court. The Medicare federal question issue concerns whether the putative "state law" AWP claims advanced on behalf of Medicare beneficiaries require the resolution of a "substantial federal question" under *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9 (1983) (state law claims "arise under" federal law "where the vindication of a right under state law necessarily turn[s] on some construction of federal law."). As noted in defendants' Status Report of April 4, 2003, this jurisdictional issue is present in six AWP cases pending before the Court, including the State of Minnesota case, and eight cases soon to be before the Court.²

¹ These defendants are: GlaxoSmithKline; Pharmacia Corp.; Aventis Pharmaceuticals Inc.; Dey, Inc.; Roxane Laboratories, Inc.; Warrick Pharmaceuticals Corp.; Schering-Plough Corp.; and Schering-Corp.

² This Medicare issue is present in six cases pending before the Court: *State of Minnesota v. Pharmacia Corp.*, Case No. 0:02-1779 (D. Minn.); *Congress of California Seniors v. Abbott Labs., et al.*, Case No. C02-8179 AIIM (C.D. Cal.); *Rice v. Abbott Labs., Inc., et al.*, Case No. C02-3925 MJJ (N.D. Cal.); *Thompson v. Abbott Labs., Inc., et al.*, Case No. C02-4450 MJJ (N.D. Cal.); *Turner v. Abbott Labs., Inc., et al.*, Case No. C02-5006 MHP (N.D. Cal.); and *Digel v. Abbott Labs., Inc., et al.*, Case No. 03-2109 Ma BRE (W.D. Tenn.). In addition, this issue is present in eight cases soon to be before the Court: *Swanston v. TAP Pharmaceutical Products, Inc., et al.*, Case No. CIV-03-0062-PHX-SMM (D. Ariz.) (subject to JPML CTO-7); *State of New York v. GlaxoSmithKline, PLC, et al.*, Case No. 03-CV-0299 TJM DRH (N.D.N.Y.); *State of New York v. Pharmacia Corp.*, Case No. 3:03-CV-0295 DNH DHH (N.D.N.Y.) (subject to JPML CTO-10); *State of New York v. Aventis Pharmaceuticals, Inc.*, Case No. 03-CV-0305 NAM RFT (N.D.N.Y.) (subject to JPML CTO-11); *State of Connecticut v. GlaxoSmithKline, PLC, et al.*, Case No. 3:03-CV-0553 (JCH) (D. Conn.) (subject to JPML CTO-11); *State of Connecticut v. Pharmacia Corp.*, Case No. 3:03-CV-0554 (JCII) (D.Conn.) (subject to JPML CTO-11); *State of Connecticut v. Aventis Pharmaceuticals Inc.*, Case No. 3:03-CV-0557 (JCH) (D. Conn.) (subject to JPML CTO-11); and *State of Connecticut v. Dey, Inc., et al.*, Case No. 3:03-CV-0572 (JCH) (subject to JPML CTO-11).

This issue was also fully briefed recently in the Connecticut and New York Attorney General actions, which are en route to this Court. In Part I, we summarize our arguments in opposition to the remand motions in these cases. In Part II, we demonstrate why the Court's May 13 Memorandum and Order further supports federal question jurisdiction over the state law claims advanced on behalf of Medicare beneficiaries.

I. THE STATE LAW CLAIMS BROUGHT ON BEHALF OF FEDERAL MEDICARE BENEFICIARIES PRESENT SUBSTANTIAL FEDERAL QUESTIONS BECAUSE THEY "NECESSARILY TURN ON" AN INTERPRETATION OF THE TERM "AWP" UNDER THE MEDICARE STATUTE AND REGULATIONS.

As defendants asserted in the New York and Connecticut Attorney General AWP cases, the claims of Medicare beneficiaries present a substantial federal question for three reasons.

First, state law claims "arise under" federal law "where the vindication of a right under state law necessarily turn[s] on some construction of federal law." *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9 (1983); *see also Almond v. Capital Properties, Inc.*, 212 F.3d 20, 23 (1st Cir. 2000) (federal question jurisdiction exists where "regardless of whether federal or state law creates the claim, a well-pleaded complaint necessarily requires resolution of a substantial question of federal law") (internal quotation marks omitted). In the Minnesota, New York, and Connecticut cases, as with the other AWP cases in which state law claims are brought on behalf of Medicare beneficiaries, the state law claims "necessarily turn" on the construction of a statutory term, AWP, in a federal statute, requiring the Court to "evaluate the scope" of the defendants' obligations to the Medicare program and its beneficiaries. Put another way, if resolution of a state law claim requires a court to construe a federal statute or "evaluate the scope" of a defendant's obligations under federal law, federal question jurisdiction exists. *See D'Alessio v. New York Stock Exch., Inc.*, 258 F.3d 93, 100-02 (2d Cir. 2001) (federal

question jurisdiction existed because resolution of plaintiff's state law claims required construction of "federal securities laws"); *Ormet Corp. v. Ohio Power Co.*, 98 F.3d 799, 807 (4th Cir. 1996) (federal question jurisdiction existed because resolution of plaintiff's claims required court to construe Title IV of the Clean Air Act); *Still v. DeBuono*, 927 F. Supp. 125, 128-29 (S.D.N.Y. 1996) (federal question jurisdiction existed because resolution of plaintiff's claims required court to construe Individuals with Disabilities Education Act). In fact, the claims on behalf of Medicare beneficiaries can be determined *only* by reference to the Medicare Act and the accompanying regulatory and legislative history. The only way to decide whether the federal Medicare program and its beneficiaries have been defrauded or deceived under the AWP system is by defining and construing the statutory term AWP. State law is silent on that question.

Second, as a consequence, federal law provides the most essential element of the state law claims on behalf of Medicare beneficiaries. Federal question jurisdiction exists where the federal question serves as an "essential element" of the state law claim. *See, e.g., San Juan Legal Servs. Inc. v. Legal Servs. Corp.*, 655 F.2d 434, 437 (1st Cir. 1981) (federal jurisdiction existed because federal law -- namely the regulations promulgated by the Legal Services Corporation pursuant to 42 U.S.C. § 2996 -- was a necessary element of plaintiffs' cause of action); *In re Universal Serv. Fund Tel. Billing Practices Litig.*, 2002 WL 31929179 (D. Kan. Dec. 19, 2002) (federal jurisdiction existed because plaintiff's reliance on Federal Communications Act was an "essential element" of the state law claim); *Still*, 927 F. Supp. at 128-29 (interpretation of Individuals with Disabilities Education Act was an "essential element" of plaintiff's claims); *County of Suffolk v. Long Island Lighting Co.*, 549 F. Supp. 1250, 1256 (E.D.N.Y. 1982) (plaintiff's reliance on federal law was an "essential element" in establishing right to relief, thus federal question jurisdiction existed).

Third, federal question jurisdiction exists where the state law claims derive from rights “created by federal law.” *W. 14th St. Commercial Corp. v. 5 W. 14th Owners Corp.*, 815 F.2d 188, 196 (2d Cir. 1987) (federal question jurisdiction exists where “the vindication of rights and definition of relationships created by federal law depends” on the construction of federal law). Thus, if the state law claims would not exist but for the federal statute in question, the claims arise under federal law. *See City of New York v. Ruppel Assocs.*, 703 F. Supp. 284, 287 (S.D.N.Y. 1989) (“Without the federal statute and federal regulations, the right asserted by the [plaintiff] in this suit would never have existed.”). In all of the cases where state law claims are asserted on behalf of Medicare beneficiaries, if the Medicare statute never existed, the Medicare beneficiaries would have no claim of AWP fraud. The Medicare AWP system is what gives rise to the alleged claims by the Medicare beneficiaries in these cases. Under these circumstances, the state law claims “arise under” federal law for purposes of Section 1331. *Id.*³

Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 810 (1986), does not undermine this conclusion. In *Merrell Dow*, the Court found federal question jurisdiction lacking because the federal statute at issue (the Food, Drug and Cosmetic Act) was merely “an element” of the state law claims. *Merrell Dow*, 478 U.S. at 812. By contrast, in the AWP cases, the question of whether it was fraud or a “deceptive practice” to report allegedly inflated prices

³ There are other bases supporting federal question jurisdiction over the AWP claims being asserted around the country, including ERISA complete preemption. Although this Court concluded that ERISA did not completely preempt *all* of MDL plaintiffs’ state law claims, the Court acknowledged that ERISA may completely preempt *some* state law claims. Mem. and Order at 38. It is, of course, well settled that where some state law claims are completely preempted, a court can assert supplemental jurisdiction over the remaining claims. *See, e.g., Roark v. Humana, Inc.*, 307 F.3d 298, 312 (5th Cir. 2002) (where complaint states at least one claim that is completely preempted by ERISA, a court may assert jurisdiction over the remaining, non-preempted claims); *Darcangelo v. Verizon Comm., Inc.*, 292 F.3d 181, 187 (4th Cir. 2002) (same).

can be determined *only* by reference to the Medicare Act and the accompanying regulatory and legislative history. For the Medicare claims, federal law is more than an "element" -- the state law claims would not even exist but for the federal AWP statute. Thus, *Merrell Dow* does not support remand in these AWP cases.⁴

II. THE COURT'S MAY 13 MEMORANDUM AND ORDER FURTHER SUPPORTS FEDERAL QUESTION JURISDICTION.

The Court's recent opinion further supports federal question jurisdiction. The Court stated that the state law claims advanced in the MDL on behalf of Medicare beneficiaries will require "the heartland task of construing" the "statutory language" of the Medicare AWP provision. Mem. and Order at 11. In considering this statutory language, the Court will utilize traditional tools of statutory construction such as the relevant legislative and regulatory history behind AWP. Thus, in order for any plaintiff to prevail on a state law claim brought on behalf of Medicare beneficiaries, the Court will have to interpret a federal statute using the federal regulatory history and Congressional intent. Under these circumstances, the state law claims advanced by Medicare beneficiaries arise under federal law. *See D'Alessio*, 258 F.3d at 100-02 (federal question jurisdiction existed because resolution of plaintiff's state law claims required construction of "federal securities laws").

Moreover, this Court's recent ruling that the state law claims were not preempted by the Medicare statute does not mean that claims of AWP fraud made on behalf of Medicare beneficiaries do not present a substantial federal question. First, the legal standard for whether a state law claim is preempted by federal law is analytically distinct from that used to determine

⁴ In its May 13 Memorandum and Order, the Court cited *Merrell Dow* only for the proposition that the need for uniformity in the application of a federal statute is an insufficient ground, standing alone, to find that the state law claims were preempted. Mem. and Order at 31.

whether a state law claim is removable because it raises a substantial federal question. *See, e.g., Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318 (Fed. Cir. 1998) (“The jurisdictional and preemption analyses, although both intimately linked to congressional intent, pose different questions drawn from different statutory provisions.”), *overruled on other grounds, Midwest Indus., Inc. v. Karavan Trackers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999). Preemption is a defense to a state law claim that if successfully asserted results in the dismissal of state law claims. *See, e.g., Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987). The *Franchise Tax Board* “substantial federal question” analysis, by contrast, does not involve whether the Medicare statute preempts “the entire field” of pharmaceutical price reporting, or whether the maintenance of the state law claims will directly conflict with the Medicare program. Instead, the Court need only determine whether the state law claims “necessarily turn on some construction of federal law.” *Franchise Tax Bd.*, 463 U.S. at 9.

Second, the purposes of the preemption analysis and the substantial federal question analysis also differ. The purpose of the preemption analysis is to determine whether a state law claim may be heard at all; a state law claim that is preempted by federal law must be dismissed. The aim of the substantial federal question analysis, by contrast, is not to determine *whether* a state law claim may be heard, but *where* it may be heard. Thus, a state law claim that raises a substantial question of federal law need not be dismissed, but can properly be adjudicated in federal court.

The *Hunter Douglas* case illustrates these differences. In *Hunter Douglas*, the Federal Circuit held that federal question jurisdiction existed over plaintiff’s state law claims because plaintiff’s right to relief depended upon the resolution of a substantial question of federal patent law. *Id.* at 1328-29. At the same time, however, the court held that the state law claims

were not preempted by federal patent law. In so holding, the court explained that the jurisdictional and preemption analyses were independent of one another:

The jurisdictional and preemption analyses, although both intimately linked to congressional intent, pose different questions drawn from different statutory provisions. Even if there is no preemption of a particular state law tort as-applied, that does not mean that Congress does not want there to be exclusive federal jurisdiction over that claim . . . Accordingly, state torts that plead a substantial question of federal patent law as a necessary element and that are not in preemptory conflict with that law belong in federal court.

Id. at 1338 (emphasis added).

Likewise, the Court's preemption ruling "does not mean" that there is no federal jurisdiction over the state law claims advanced by Medicare beneficiaries in the AWP cases. The state law claims advanced by these Medicare beneficiaries turn on a substantial question of federal Medicare law and thus belong in federal court.

ON BEHALF OF THE FOLLOWING DEFENDANTS
IN THE CONNECTICUT AND NEW YORK
ATTORNEY GENERAL ACTIONS:

BY: Mark H. Lynch ^{By 2/15}
6/1/2003

DATED: June 2, 2003

Mark H. Lynch, Esq.
Ethan M. Posner, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Telephone: (202) 662-6000
Fax: (202) 662-6291

Fredrick G. Herold, Esq.
Dechert LLP
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103
Telephone: (215) 994-2413

Fax: (215) 994-2222

Geoffrey E. Hobart, Esq.
Holland & Knight
10 St. James Avenue
Boston, MA 02116
Telephone: (617) 854-1419
Fax: (617) 523-6850

**GLAXOSMITHKLINE
PHARMACIA CORP.
AVENTIS PHARMACEUTICALS INC.
DEY, INC.
ROXANE LABORATORIES, INC.
WARRICK PHARMACEUTICALS CORP.
SCHIERING-PLOUGH CORP.
SCHERING CORP.**

CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2003, I caused a true and correct copy of this Status Report and Memorandum on the Medicare Federal Question Issue Pending in the Cases Transferred to this Court to be served on all counsel of record in MDL No. 1456 by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456. I further certify that on June 2, 2003, I caused a true and correct copy of this Status Report and Memorandum on the Medicare Federal Question Issue Pending in the Cases Transferred to this Court to be served on counsel listed below by first-class mail, postage prepaid.

Richard Blumenthal, Attorney General
Robert B. Teitelman, Assistant Attorney General
Office of the Attorney General
55 Elm Street P.O. Box 120
Hartford, CT 06141-0120

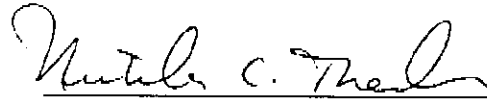
Garry H. Desjardins, Assistant Attorney General
Michael E. Cole, Assistant Attorney General
Office of the Attorney General
MacKenzie Hall
110 Sherman Street
Hartford, CT 06105

Counsel for Plaintiff State of Connecticut

Eliot Spitzer, Attorney General
Matthew Barbaro, Assistant Attorney General
Justice Building D-10 Annex
Albany, NY 12224

Rose E. Firestein, Assistant Attorney General
120 Broadway, 3rd Floor
New York, NY 10271

Counsel for Plaintiff State of New York


Nicholas C. Theodorou